



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/579,330

08/08/2006

Minas Theodore Coroneo

37528-503N01US

6478

64046

7590

07/01/2010

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C  
ONE FINANCIAL CENTER  
BOSTON, MA 02111

EXAMINER

WIEST, PHILIP R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

07/01/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,330	<b>Applicant(s)</b> CORONEO, MINAS THEODORE	
	<b>Examiner</b> Philip R. Wiest	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 19-21 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-21 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/22/10</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/22/10 has been entered.

### ***Response to Amendment***

In the reply filed 6/22/10, applicant amended claims 19 and 21. Claims 19-21 and 31 are currently pending.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 19 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not specifically state

Art Unit: 3761

that the distal end of the implant is cone-shaped such that the diameter of the distal end gradually reduces moving in the distal direction.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 19 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims first state that the “distal end has an enlarged diameter relative to the central portion”, then state that “the diameter of the distal end gradually reduces moving in a distal direction.” These statements contradict each other because an enlarged distal end necessarily has a larger diameter than the section immediately adjacent to it. For the purposes of examination, the examiner has interpreted this limitation to mean that the **enlarged portion of the distal end** (i.e. the enlarged anchor portion) is substantially cone-shaped such that the diameter gradually decreases moving in a distal direction.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3761

3. Claims 19, 21, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Solomon (US 5,626,559).

4. With respect to Claim 19 and 21, Solomon teaches an ocular pressure spike shunt comprising a fluid transfer tube made from a biocompatible, substantially flexible material such as silicone or Teflon (Column 2, Lines 23-28). The tube has an inner (distal) end 26, an outer (proximal) end 12', a tubular lumen 14 disposed therebetween, and a one-way valve 36 for maintaining pressure in the eye at a normal level, said valve opens to permit fluid flow through the tube when a predetermined pressure is exceeded (Column 2, Lines 61-65). When implanted in the eye, the shunt is disposed such that the outer end is substantially flush with the outer surface of the cornea, and the inner end opens into the anterior chamber of the eye on the inner surface of the cornea. The implant is fully capable of being inserted into an ocular paracentesis incision port and removed from the eye after treatment is complete. See Figures 1-5. Regarding claim 21, Solomon teaches a method of implanting an ocular shunt as described above, comprising forming an incision in the eye, and introducing the shunt through the incision such that the outer end is flush with the surface of the cornea and the inner surface extends into the anterior chamber of the eye (see Abstract). Solomon further teaches an anchoring means at both ends of the tube (proximal anchor 12 at the proximal end and distal anchor 28 at the distal end), said anchoring means comprising enlarged diameters. The proximal anchor 12 comprises edges that are substantially flush with the outer surface of the cornea upon implantation, and the distal anchor comprises an enlarged diameter 28 that is positioned flat against the inner surface of the cornea.

Art Unit: 3761

Further, Solomon teaches that the distal end of the shunt (i.e. the distal anchor) is cone-shaped, such that the diameter of the distal tip is smaller than the rest of the anchor (see Figure 1).

5. With specific respect to Claim 31, Solomon teaches one embodiment (Figure 3) wherein the tubular portion has a length that is substantially equal to the thickness of the cornea. Solomon clearly teaches that the implant is designed such that the implant is sized such that the proximal and distal anchors abut the outer and inner walls of the cornea, respectively. The tubular portion therefore has a length that corresponds to the cornea's thickness (see entire disclosure).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon in view of Brown et al. (US 5,743,868). Solomon teaches the ocular shunt substantially as claimed, and further teaches that the unidirectional valve is configured to open when fluid in the anterior chamber exceeds a predetermined pressure (Column 2, Lines 61-65). Solomon, however, does not specifically teach that the unidirectional valve

Art Unit: 3761

operates such that a 10 mmHg pressure differential is maintained. Brown discloses an ocular implant for regulating pressure between the anterior chamber and the exterior of the cornea such that the pressure difference is kept at 10 mmHg, which is considered to be a normal pressure in the anterior chamber (Column 6, Lines 37-44). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the unidirectional pressure control valve of Solomon to regulate fluid flow such that a 10 mmHg pressure differential is maintained in order to keep the anterior chamber of the eye at a natural pressure level.

### ***Response to Arguments***

Applicant's arguments have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly considered prior art.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R. Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Philip R Wiest/  
Examiner, Art Unit 3761

/Leslie R. Deak/  
Primary Examiner, Art Unit 3761  
30 June 2010